

# Exhibit C

In The Matter Of:

***Rackliff vs. C.R. Bard***

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***Suzanne Parisian, M.D.***

June 13, 2014

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1 exempt snare, which is a different device. It's not  
2 specific for any type of unit, but it can injure, too.  
3 That's why not all filters can be recovered. They have  
4 to have -- some of our clients have had to have it  
5 surgically removed because you cannot recover with the  
6 filter.

7 Q In any of the cases that you've been  
8 specifically retained in, have you seen any indication  
9 that the Recovery Cone was implicated in a particular  
10 patient's injuries?

11 A No, not in the cases I have.

12 Q Have you read any medical literature where the  
13 Recovery Cone was implicated with a patient's injuries?

14 A I haven't looked for that. I haven't focused  
15 on that. I know that -- I haven't focused on that.

16 Q Okay. It's your opinion that the Recovery  
17 filter was adulterated and misbranded?

18 A Yeah. It didn't perform as cleared. It was  
19 cleared as a -- as a permanent filter, and it did not  
20 perform as a -- it didn't perform like the SNF or any  
21 other permanent filter.

22 Q Now --

23 A So that makes it adulterated right there.  
24 It's not the device that's cleared.

25 Q Prior --

1 report, I think they had signals that there was an  
2 issue with the Recovery filter early on in terms of it  
3 not performing like the cleared product, and they  
4 didn't respond in a -- in a timely manner to ensure the  
5 safety of the public. So that would be a criticism.

6 In terms of their complaint handling,  
7 failure investigation, letting products stay out on the  
8 market, which was -- were out of spec, not conducting a  
9 recall, removing product from the market that was not  
10 performing the way it was designed, not notifying  
11 physicians about the potential risks, not ensuring that  
12 patients were handed these filters that explanted in a  
13 timely manner, those are criticisms. I would look at  
14 that as criticisms of quality assurance post-market  
15 marketing.

16 And then also in terms of quality  
17 assurance, some of the -- the labeling in terms of  
18 marketing because that would be some of the claims that  
19 they are making about the product. Again, that would  
20 feed into physician.

21 Q Have you seen any evidence that there -- Bard  
22 did not appropriately follow federal regulations in how  
23 it -- in its complaint handling process?

24 A Well, now when you say follow federal  
25 regulations, that sounds like a legal conclusion. I

1 think the courts usually determine that; the judge,  
2 jury, people about that.

3 In terms of what the regulations require  
4 as far as if I was a consultant explaining what the  
5 regulations, yes, I would -- I would have said that  
6 they should have recalled the product. And I think I  
7 said it in my report in 2004, because to me, it's a  
8 prohibited act to sell a product that's adulterated and  
9 misbranded. It's not behaving as cleared in a 510(k).

10 Q I'm not talking about what kind of moves as  
11 far as the commercial sale of the product. I'm talking  
12 about complaint handling. The FDA has requirements  
13 that when a manufacturer receives notice of an adverse  
14 event or a potential adverse event, they are required  
15 to investigate it. Isn't that correct?

16 A Yes, they are, and that's just part of quality  
17 systems 21 CFR 820.

18 Q And they then have to submit a MDR, a medical  
19 device report, to the FDA regarding that investigation,  
20 correct?

21 A No, not necessarily. 21 CFR 803 allows the  
22 company to make a determination of whether something is  
23 reportable or not reportable. Oftentimes companies  
24 will say if something is in a label, then it's not  
25 reportable.

1           Q       BY MR. NORTH: And so it's your opinion that  
2       its off-labeled use of the Recovery filter in 2004 to  
3       implant it in a patient contraindicated for  
4       anticoagulation and with a history of recurrent  
5       pulmonary embolus if they are likewise a bariatric  
6       surgery patient?

7                       MR. LOPEZ: Objection to the form.

8                       THE WITNESS: Well, that's a different  
9       question, because now you are going through the  
10      indicated use. It could be because the company knows  
11      they have done no research on anything about a  
12      bariatric patient. And a bariatric patient is  
13      anatomically totally different than a patient of normal  
14      weight. And so there are new risks in terms of the --  
15      and the company knows there is risks in terms of the  
16      inferior vena cava, and they've done no research.

17                      So let the doctor know they've done no  
18      research to make sure it's safe. He may want to put in  
19      something else. He may want to consider whether she  
20      should be on heparin, or the patient. So let the  
21      doctor know that this has never been looked at for this  
22      patient population. Don't just give him something and  
23      tell him or her that it's safe to give for a bariatric  
24      patient, and then when the bariatric patient dies, they  
25      go, well, they were bariatric patients. They were

1 morbidly obese. They had clots.

2                   You can't do that. That's not -- that's  
3 not allowed in terms of the requirements. It's a  
4 prohibited act to sell a device that's not safe and  
5 effective and adequately labeled. You are not  
6 adequately informing the physician about this device  
7 before he implants it in a patient.

8           Q     BY MR. NORTH: Is it your opinion that the  
9 Recovery filter should have been contraindicated in all  
10 morbidly obese patients?

11           A     Theoretically that would have been one option  
12 for Bard, particularly since they knew in 2004 the  
13 complications in bariatric populations were common and  
14 that they had somehow been involved in promotion of it  
15 for bariatric use, and now it wasn't safe and  
16 attracting deaths.

17                   So to contraindicate it would have  
18 been -- made perfect sense. It would have been an  
19 option for Bard, and they could go into the FDA and  
20 say, you know, we are aware of off-labeled use. We  
21 have never tested it for this. These patients are  
22 dying. To protect public health, we are going to make  
23 a change in our label and contraindicate it for our  
24 patients using our filter. So that would have been one  
25 option for Bard to protect safety.